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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,115	03/31/2004	Darin G. Schaeffer	8627/331	6599

757 7590 04/17/2007
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EXAMINER	
POUS, NATALIE R	
ART UNIT	PAPER NUMBER
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/815,115	SCHAEFFER ET AL.	
	Examiner	Art Unit	
	Natalie Pous	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29 and 31-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29 and 31-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ~~8/29/06~~ *3/31/04*. 8/24/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Regarding the 102 rejections

Applicant's arguments, see pages 10-15, filed 3/12/07, with respect to the rejection(s) of the claims under 35 USC 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Camrud et al '117.

Regarding the combination of Camrud '117 and Kocur

Applicant argues that the principal operation of Kocur is completely different than the claimed invention. Examiner respectfully disagrees. As disclosed in the previous office action, both Camrud '117 and Kocur teach stent structures for placement into a body lumen, and further both comprise a portion which is meant to hold the stent structure in one configuration upon deployment, and subsequently degrade over time to allow the stent structure to assume another configuration. In this manner, both Camrud '117 and Kocur teach the same principal of operation, and examiner sustains that the combination of these two references is proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1, 2, 4, 7, 8, 9, 12, 17, 18, 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Camrud et al. (US 6258117), embodiment of figures 7a-7b, hereinafter Camrud 7 in view of Camrud et al. (US 6258117), embodiment of figures 5a-5b, hereinafter Camrud 5.

Camrud 7 teaches an expandable stent comprising:

- a plurality of substantially cylindrical, serpentine ring structures (12, 14, 16, 18), wherein each ring structure extends around a circumference of the stent and comprises at least one unit structure, wherein said at least one unit structure comprises a plurality of strut members and a plurality of bends, said strut members and bends forming a substantially zig-zag pattern (fig. 7a); and at least one connector (113) member which is biodegradable disjoined.
- wherein said stent is a substantially integral, tubular shape in said unexpanded state (fig. 7a)
- wherein said at least one connector member is made of one or more of polymers, copolymers, block polymers, poly-lactic acid, poly-glycolic acid, polyglycolides, polylactides, polycaprolactones, polyglycerol sebacate, polycarbonates,

polyethylene oxide, polybutylene terepthalate, polydioxanones, hybrids, composites, collagen matrices with growth modulators, proteoglycans, glycosaminoglycans, vacuum formed small intestinal submucosa, fibers, chitin, and dextran (Column 9, proximate lines 14-22).

- wherein said at least one connector member (113) comprises one layer having a substantially uniform degradation rate.
- wherein said ring structures are made of one or more of nitinol, stainless steel, 316 L stainless steel, cobalt chromium, nickel titanium, platinum, and inconel (Column 5, proximate lines 55-60).
- wherein said ring structures comprise a non-biodegradable base material and one or more biodegradable coating layers (Column 5, proximate lines 34-53).
- wherein said ring structures comprise one biodegradable coating layer having a uniform degradation rate (Column 5, proximate lines 34-53).
- wherein said stent is one of self-expanding and balloon-expandable (Column 7, proximate lines 15-24).
- wherein when said stent is in an unexpanded state there are two or more connector members joining said two ring structures and adjacent connector members are circumferentially aligned (fig. 7a).
- wherein adjacent ring structures are axially aligned (fig. 7a).•

Camrud 7, fails to teach wherein the at least one connector member is straight and joins two of said ring structures when said stent is in an unexpanded state, wherein

said at least one connector member is biodegradable and adapted to biodegrade when said stent is in an expanded state so that said two ring structures become substantially disjoined. Camrud 5 teaches an expandable stent comprising a plurality of substantially cylindrical, serpentine ring structures, further comprising at least one straight connector member (90) joining two of said ring structures when said stent is in an unexpanded state, wherein said at least one connector member is biodegradable and adapted to biodegrade when said stent is in an expanded state in order to allow the ring structures to move freely to effectively adapt to the body lumen, upon degradation of the connecting member. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Camrud 7 with at least one connector member joining two of said ring structures when said stent is in an unexpanded state, wherein said at least one connector member is biodegradable and adapted to biodegrade when said stent is in an expanded state as seen in Camrud 5 in order to allow the ring structures to move freely to effectively adapt to the body lumen, upon degradation of the connecting member.

The combination of Camrud 7 and Camrud 5 further teaches wherein when said stent is in an unexpanded state said at least one connector member has first and second ends, said first end being connected to one of said plurality of bends of one of said two ring structures and said second end being connected to another of said plurality of bends of the other of said two ring structures.

Claims 5, 10, 27-29, 32-35, 37, 42, 43 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Camrud 7 in view Camrud 5, and further in

view of Kocur. The combination of Camrud 7 and Camrud 5 teaches all limitations of preceding dependent claims 1 and 9 as previously described.

Camrud 7 teaches a method of expanding a stent comprising:

- providing an expandable stent which in an unexpanded state comprises a plurality of substantially cylindrical, serpentine ring structures (12, 14, 16, 18), wherein each ring structure extends around a circumference of the stent, and at least one biodegradable connector (113) member; delivering the stent in an unexpanded state to a final destination within a mammalian body; expanding the stent;
- wherein, each ring structure extends around a circumference of the stent and comprises at least one unit structure, wherein said at least one unit structure comprises a plurality of strut members and a plurality of bends, said strut members and bends forming a substantially zig-zag pattern (fig. 7a).
- wherein said at least one connector member is made of one or more of polymers, copolymers, block polymers, poly-lactic acid, poly-glycolic acid, polyglycolides, polylactides, polycaprolactones, polyglycerol sebacate, polycarbonates, polyethylene oxide, polybutylene terepthalate, polydioxanones, hybrids, composites, collagen matrices with growth modulators, proteoglycans, glycosaminoglycans, vacuum formed small intestinal submucosa, fibers, chitin, and dextran (Column 9, proximate lines 14-22).
- wherein said at least one connector member (113) comprises one layer having a substantially uniform degradation rate.

- wherein said ring structures are made of one or more of nitinol, stainless steel, 316 L stainless steel, cobalt chromium, nickel titanium, platinum, and inconel (Column 5, proximate lines 55-60).
- wherein said ring structures comprise a non-biodegradable base material and one or more biodegradable coating layers (Column 5, proximate lines 34-53).
- wherein said ring structures comprise one biodegradable coating layer having a uniform degradation rate (Column 5, proximate lines 34-53).
- wherein said stent is one of self-expanding and balloon-expandable (Column 7, proximate lines 15-24).

Camrud 7, fails to teach wherein the at least one connector member is straight and joins two of said ring structures when said stent is in an unexpanded state, wherein said at least one connector member is biodegradable and adapted to biodegrade when said stent is in an expanded state so that said two ring structures become substantially disjoined. Camrud 5 teaches an expandable stent comprising a plurality of substantially cylindrical, serpentine ring structures, further comprising at least one straight connector member (90) joining two of said ring structures when said stent is in an unexpanded state, wherein said at least one connector member is biodegradable and adapted to biodegrade when said stent is in an expanded state in order to allow the ring structures to move freely to effectively adapt to the body lumen, upon degradation of the connecting member. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Camrud 7 with at least one connector member joining two of said ring structures when said stent is in an unexpanded state, wherein

said at least one connector member is biodegradable and adapted to biodegrade when said stent is in an expanded state as seen in Camrud 5 in order to allow the ring structures to move freely to effectively adapt to the body lumen, upon degradation of the connecting member.

The combination of Camrud 5 and Camrud 5 further teaches wherein the connectors may degrade over a predetermined period of time (Column 5, proximate lines 27-33), but fails to teach wherein the connector member is adapted to biodegrade within thirty days to one-hundred eighty days after said stent is expanded. Kocur teaches a stent with a biodegradable portion that may degrade over a period of time of within thirty days to one-hundred eighty days after implementation (Columns 7 and 8, proximate lines 62-67, and 1-8 respectively) in order to allow for the desired degradation time whether it be quickly or delayed. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the degradation time of within thirty days to one-hundred eighty days as taught by Kocur in order to allow for the desired degradation time whether it be quickly or delayed.

Claims 19 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Camrud 7 and Camrud 5, or the combination of Camrud 7, Camrud 5 and Kocur, and further in view of Hong et al. (US 6565599).

The combination of Camrud 7 and Camrud 5, or the combination of Camrud 7, Camrud 5 and Kocur teach all limitations of preceding dependent claims 1 and 27, as previously described, but fail to teach wherein said at least one connector member is flexible prior to the stent being expanded. Hong teaches a stent comprising radial

sections connected by flexible links in order to provide longitudinal flexibility of the stent during deployment. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Camrud 7 and Camrud 5, or the combination of Camrud 7, Camrud 5 and Kocur with flexible links as taught by Hong in order to provide longitudinal flexibility of the stent during deployment.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Camrud 7 and Camrud 5, and further in view of Evans et al. (US 6102938).

The combination of Camrud 7 and Camrud 5 teaches all limitations of preceding dependent claim 1 as previously described, but fails to teach wherein said stent is substantially Y-shaped when in said unexpanded state. Evans teaches a stent having a Y-shaped configuration when in an unexpanded state (82) in order to provide a stent for use in the aortic and iliac arteries. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Camrud 7 and Camrud 5 with a Y-shaped configuration as taught by Evans in order to provide a stent for use in the aortic and iliac arteries.

Claims 13, 14 16, 38, 39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Camrud 7 and Camrud 5, or the combination of Camrud 7, Camrud 5 and Kocur, and further in view of Wu et al. (US 6254632)
The combination of Camrud 7 and Camrud 5, or the combination of Camrud 7, Camrud 5 and Kocur teach all limitations of preceding dependent claims 1 and 27 as previously described, and further teach wherein the ring structures comprise a base material made

of a combination of non-biodegradable materials and biodegradable materials (Camrud Column 5, proximate lines 34-53), and further teach wherein the biodegradable polymers biodegrade within thirty days to one-hundred eighty days after the stent is expanded, but fail to teach wherein the biodegradable material is a polymer. Wu teaches a stent having a base material made of a combination of non-biodegradable material (114) and biodegradable polymer materials (420) in order to provide controlled release of a therapeutic substance (410). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Camrud 7 and Camrud 5, or the combination of Camrud 7, Camrud 5 and Kocur with a polymeric material as taught by Wu in order to provide controlled release of a therapeutic substance.

Claims 6, 11, 15, 31, 36 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Camrud 7 and Camrud 5, or the combination of Camrud 7, Camrud 5 and Kocur, or Camrud 7, Camrud 5 and Wu, or the combination of Camrud 7, Camrud 5, Kocur and Wu and further in view of Sirhan et al. (US 7077859). The combination of Camrud 7 and Camrud 5, or the combination of Camrud 7, Camrud 5 and Kocur, or Camrud 7, Camrud 5 and Wu, or the combination of Camrud 7, Camrud 5, Kocur and Wu teach all limitations of preceding dependant claims 1, 9, 10, 13, 27, 34 and 38 as described previously, but fail to teach wherein the connector or coating layers are formed with layers having multiple biodegradable layers with different degradation rates. Sirhan teaches an implanted prosthesis having multiple biodegradable layers with different degradation rates in order to allow for programmed and controlled

degradation of layers to achieve a desired purpose. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Camrud 7 and Camrud 5, or the combination of Camrud 7, Camrud 5 and Kocur, or Camrud 7, Camrud 5 and Wu, or the combination of Camrud 7, Camrud 5, Kocur and Wu with multiple layers having varying degradation rates in order to allow for programmed and controlled degradation of layers to achieve a desired purpose.

Claims 20, 21, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Camrud 7 and Camrud 5, or the combination of Camrud 7, Camrud 5 and Kocur, and further in view of Camrud et al (US 6485510), hereinafter Camrud '510.

The combination of Camrud 7 and Camrud 5, or the combination of Camrud 7, Camrud 5 and Kocur teach all limitations of preceding dependent claims 1 and 27, but fail to teach wherein said at least one connector member is substantially curved, U or V shaped. Camrud '510 teaches a multi section stent that separates into independent portions upon deployment comprising connecting portions (215) that are substantially curved, U or V shaped in order to provide for increased flexibility during deployment. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Camrud 7 and Camrud 5, or the combination of Camrud 7, Camrud 5 and Kocur as taught by Camrud '510 in order to provide for increased flexibility during deployment.

Claims 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Camrud '510 in view of Camrud 5.

Camrud 510 teaches the following:

- A plurality of substantially cylindrical ring structures (205), wherein each ring structure extends around a circumference of the stent and comprises at least one unit structure; and at least one connector member (215) joining two of said ring structures when said stent is in an unexpanded state, said connector member being curved (fig. 20)
- Wherein said at least one connector member is substantially U or V shaped (fig. 20)
- Said connector member (215) being elongate and extending across a space separating adjacent ring structures (fig. 18)
- Said connector member comprising a first end joined to one ring structure and a second end joined to an adjacent ring structure

Camrud '510 fails tot each wherein said at least one connector member is biodegradable and adapted to biodegrade when said stent is in an expanded state. Camrud 5 teaches an expandable stent comprising a plurality of substantially cylindrical, serpentine ring structures, further comprising at least one connector member (90) joining two of said ring structures when said stent is in an unexpanded state, wherein said at least one connector member is biodegradable and adapted to biodegrade when said stent is in an expanded state in order to allow the ring structures to move freely to effectively adapt to the body lumen, upon degradation of the connecting member. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Camrud 7 with at least one connector member joining two of said ring

structures when said stent is in an unexpanded state, wherein said at least one connector member is biodegradable and adapted to biodegrade when said stent is in an expanded state as seen in Camrud 5 in order to allow the ring structures to move freely to effectively adapt to the body lumen, upon degradation of the connecting member.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
4/6/07

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4/9/07.